UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/612,921	07/10/00	SIMS J	03260.0047

EXAMINER	
PRASAD,S	
ART UNIT	**PAPER NUMBER**
1646	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application No.	Applicant(s)	
	09/612,921	SIMS, JOHN E.	
	Examiner	Art Unit	
	Sarada C Prasad	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims *13-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Re-Restriction/Election

1. Receipt of election of invention of Group I (claims 13-24, 35-36) in response to restriction requirement in Paper No. 5 (2/5/01) is acknowledged.

However upon further consideration, the Applicant is required to specify one specific nucleotide or polypeptide sequence for examination. This requirement is made under 1192 O.G. 68 Notice (November 19, 1996), as the examination of more than one sequence in one application would result in an undue burden on the PTO.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 13-15, 22-24, and 35 are drawn to nucleic acid encoding IL-1 delta, vectors, host cells and expression systems for production of the instant polypeptides and a method for production of human polypeptides (SEQ.ID.NO.4 and 3), classified in class 435, subclass 69.1.

Group II. Claims 16-21, and 36 are drawn to nucleic acid encoding IL-1 delta, vectors, host cells and expression systems for production of the instant polypeptides and a method for production of murine polypeptides (SEQ.ID.NO.2 and 1), classified in class 435, subclass 69.1.

Group III. Claims 25, 26, 31-34, 41 are drawn to the human polypeptide products of IL-1 delta (SEQ ID NO. 4) , and a kit for determination of molecular weights of the peptides, classified in class 530, subclass 350.

Group IV. Claims 27-30 are drawn to the murine polypeptide products of IL-1 delta (SEQ ID NO. 2), and a kit for determination of molecular weights of the peptides, classified in class 530, subclass 350.

Group V. Claims 37-38 are drawn to antibodies to IL-1 delta polypeptides (SEQ.ID.NO. 2) classified in class 530, subclass 388.23.

Group VI. Claims 39-40 are drawn to antibodies to IL-1 delta polypeptides (SEQ.ID.NO. 4), classified in class 530, subclass 388.23.

The inventions are distinct, each from the other because:

Inventions in Groups I, III, and V are distinct and encompass products that are structurally, physically, and functionally distinct, and if determined to be patentable they would also be patentably distinct. For example, the nucleic acids of Group I can be used to make hybridization probes or can be used in gene therapy as well as production of proteins; the protein products of Group III can be used to obtain antibodies or in developing ligand-binding assays; the antibodies of Group V can be used therapeutically or diagnostically, e.g. in screening. Therefore, these Groups I-III (using SEQ IDs 4 and 3) are not required one for the practice of the other.

In a similar fashion, comparable inventions in Groups II, IV, and VI using SEQ IDs 2 and 1 are distinct and encompass products that are structurally, physically, and functionally distinct, and if determined to be patentable they would also be patentably distinct. For example, the nucleic acids of Group II can be used to make hybridization probes or can be used in gene therapy as well as production of proteins; the protein products of Group IV can be used to obtain antibodies or in developing ligand-binding assays; the antibodies of Group VI can be used therapeutically or diagnostically, e.g. in screening.

These above inventions I-VI are so grouped in order to have only one SEQ ID, either polynucleotide or polypeptide, in each group for examination purposes. Furthermore, no matter

which group the Applicant elects, the Applicant is required to specify one specific nucleotide or polypeptide for examination. This requirement is made under 1192 O.G.68 Notice (November 19, 1996), as examination of more than one sequence in one application would result in an undue burden on the PTO.

Inventions in Groups I, II, and III, IV are related as process of making and the product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the IL-1 delta polypeptides of Groups III and IV can be made by a materially different process other than with the use of the nucleic acid of Groups I and II or its isolation form nature using various isolation/purification/chromatographic procedures or chemical synthesis.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different searches are required for inventions I-VI. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.
Examiner
Art Unit 1646
March 01, 2001

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER